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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,427	07/06/2007	Hans Meijer	P2107-295	1950
2352 7590 09/21/2009 OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403				
EXAMINER				
DEBERRY, REGINA M				
ART UNIT		PAPER NUMBER		
1647				
MAIL DATE		DELIVERY MODE		
09/21/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/584,427

**Applicant(s)**

MEIJER ET AL.

**Examiner**

Regina M. DeBerry

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-64 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I**, claim(s) 1-40, drawn to a method of producing and isolating EPO.

**Group II**, claim(s) 41, drawn to a method of highly purifying EPO.

**Group III**, claim(s) 42-48, 50, 51 and 53, drawn to EPO.

**Group IV**, claim(s) 49 and 52, drawn to EPO and a compound.

**Group V**, claim(s) 54, 60-62, drawn to a method of treating and preventing diseases curable with EPO comprising administering EPO.

**Group VI**, claim(s) 55, drawn to a method of treating and preventing a condition as recited comprising administering EPO.

**Group VII**, claim(s) 56, drawn to a method of improving oxygenation, physical performance, autologous blood donation and maintaining/increasing hematocrit comprising administering EPO.

**Group VIII**, claim(s) 57, drawn to a method of treating and preventing conditions as recited comprising administering EPO.

**Group IX**, claim(s) 58, drawn to a method of inducing, stimulating and/or supporting functions as recited comprising administering EPO.

**Group X**, claim(s) 59, drawn to a method of producing a hormonal effect comprising administering EPO.

**Group XI**, claim(s) 63, drawn to a method of administering an EPO, produced by autologous cells/tissues, to the donor of said cells/tissues.

**Group XII**, claim(s) 64, drawn to a method of making a medicament comprising EPO.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is a method of producing and isolating EPO. The special technical feature of Group II is a method of highly purifying EPO. The special technical feature of Group III is EPO. The special technical feature of Group IV is EPO and a compound. The special technical feature of Group V is a method of treating and preventing diseases curable with EPO comprising administering EPO. The special technical feature of Group VI is a method of treating and preventing a condition as recited comprising administering EPO. The special technical feature of Group VII is a method of improving oxygenation, physical performance, autologous blood donation and maintaining/increasing hematocrit comprising administering EPO. The special technical feature of Group VIII is a method of treating and preventing conditions as recited comprising administering EPO. The special technical feature of Group IX is a method of inducing, stimulating and/or supporting functions as recited comprising administering EPO. The special technical feature of Group X is a method of producing a hormonal effect comprising administering EPO. The special technical feature of Group XI is a method of administering an EPO produced by autologous cells/tissues to the donor of said cells/tissues. The special technical feature of Group XII is a method of making a medicament comprising EPO.

Groups I-XII lack unity of invention because even though the inventions of the groups require the technical feature of the EPO produced by the method in Group I, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Goldberg et al., PNAS, Vol. 84, pages 7972-7976, 1987. Goldberg et al. teach a cell culture system (Hep3B and HepG2) that produces EPO in response hypoxia conditions. Goldberg et al. teach that Hep3B and HepG2 cell lines made readily measurable amounts of EPO as measured by RIA and bioassay (pages 7972-7973 and page 7975). Note that the first and second cell or tissue can be the same. (See at least claim 9.)

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/  
Primary Examiner, Art Unit 1647

/R. M. D./  
Examiner, Art Unit 1647

Application/Control Number: 10/584,427

Page 7

Art Unit: 1647

9/16/09